DEC 2 8 2006

Ortho-Clinical Diagnostics
a Johnson-Johnson company

100 Indigo Creek Drive
Rochester, New York 14626-5101

5.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K 063164

1. Submitter name, address, contact	Ortho-Clinical Diagnostics, Inc. 100 Indigo Creek Drive Rochester, New York 14626-5101 (585) 453-4253 Contact Person: Michael M. Byrne
2. Preparation Date	October 17, 2006
3. Device name	**Trade or Proprietary Names:** VITROS Chemistry Products THC Reagent VITROS Chemistry Products Calibrator Kit 30 VITROS Chemistry Products FS Calibrator 1 VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV & V **Common Names**: Cannabinoid (THC) assay and controls **Classification Names:** Cannabinoid test system (862.3870) Class II Clinical toxicology calibrators (862.3200) Class II Clinical toxicology control material (862.3280) Class I, VITROS DAT Performance Verifiers are assayed controls, therefore they meet the reserved criteria under Section 510(l) of the Food, Drug and Cosmetic Act.
4. Predicate Devices	The VITROS THC assay is substantially equivalent to the SYVA® EMIT® II Plus Cannabinoid Assay. The VITROS DAT Performance Verifiers are substantially equivalent to the BIO-RAD Liquichek™ Urine Toxicology Controls.

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5. Device description

The VITROS THC assay is a homogeneous enzyme immunoassay that is performed using the VITROS THC Reagent with the VITROS Calibrator Kit 30, VITROS FS Calibrator 1 and VITROS FS Diluent Pack 4 (DAT Diluent / DAT Diluent 2) on VITROS 5,1 FS Chemistry Systems.

The VITROS THC Reagent is a dual chambered package containing ready-to-use liquid reagents that are used to detect cannabinoids in urine. Sample, calibrators, and controls are automatically treated with surfactant (DAT Diluent 2) prior to addition of reagents. Treated sample is added to Reagent 1 containing antibodies reactive to delta-9-tetrahydrocannabinol (delta-9-THC), glucose-6-phosphate and nicotinamide adenine dinucleotide (NAD+), followed by Reagent 2 containing delta-9-THC labeled with the enzyme glucose-6-phosphate dehydrogenase (G6P-DH). The assay is based on competition between delta 9-THC metabolites in the treated urine sample and the delta 9 -THC labeled with the enzyme glucose-6-phosphate dehydrogenase (G6P-DH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, therefore the concentration of delta-9-THC metabolites in the urine sample is directly proportional to measured enzyme activity. Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD+) to NADH, resulting in an absorbance change that is measured spectrophotometrically at 340 nm.

VITROS Calibrator Kit 30 is prepared from human urine to which analyte, surfactant, and preservatives have been added.
The VITROS FS Calibrator 1 is composed of processed water and 0.9% w/v sodium chloride (Saline). These calibrators are used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative or semi-quantitative measurement of cannabinoids (THC).

VITROS DAT Performance Verifiers I, II, III, IV and V are prepared from a human urine pool to which analytes, surfactant, and preservative have been added. These are assayed controls used to monitor performance of the VITROS THC assay on VITROS 5,1 FS Chemistry Systems.

The VITROS FS Diluent Pack 4 (DAT Diluent/ DAT Diluent 2) is a common reagent that is used with several drugs of abuse assays to dilute calibrators and samples on the VITROS 5,1 FS System. This is a dual chambered package containing two ready-to-use liquid diluents. DAT Diluent is prepared from human urine to which organic salt, surfactants, and preservative have been added. DAT Diluent 2 is prepared from processed water to which surfactant and preservative have been added.

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5. Device description (*continued*)

The VITROS 5,1 FS Chemistry System is a clinical chemistry instrument that provides automated use of the VITROS MicroTip® and MicroSlides® range of products. The VITROS 5,1 FS System was cleared for market by 510(k) Premarket Notification (K031924).

6. Device intended uses

VITROS Chemistry Products THC Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products THC Reagent is used on VITROS 5,1 FS Chemistry Systems for the semi-quantitative or qualitative determination of cannabinoids (THC) in human urine using a cutoff of either 20 ng/mL or 50 ng/mL. Measurements obtained with the VITROS THC method are used in the diagnosis and treatment of cannabinoid use or overdose.

The VITROS Chemistry Products THC assay is intended for use by professional laboratory personnel. It provides only a preliminary test result. A more specific alternative chemical method must be used to confirm a result obtained with this assay. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when evaluating a preliminary positive result.

VITROS Chemistry Products Calibrator Kit 30: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 30 is used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative or semi-quantitative measurement of cannabinoids (THC).

VITROS Chemistry Products FS Calibrator 1: For *in vitro* diagnostic use only. VITROS Chemistry Products FS Calibrator 1 is used in conjunction with VITROS Chemistry Products Calibrator Kits to calibrate VITROS 5,1 FS Chemistry Systems.

VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV and V: For *in vitro* diagnostic use only. VITROS Chemistry Products DAT Performance Verifiers are assayed controls used to monitor performance of urine drugs of abuse screening assays on VITROS 5,1 FS Chemistry Systems.

7. **Comparison to predicate devices**

The VITROS THC assay and VITROS DAT Performance Verifiers are substantially equivalent to the SYVA® EMIT® II Plus Cannabinoid Assay (K011300 and K993984) and BIO-RAD® Liquichek™ Urine Toxicology Controls (K022707) (predicate devices) which were cleared by the FDA for in vitro diagnostic use.

The performance of the VITROS THC assay on the VITROS 5,1 FS Chemistry System was compared to the SYVA® EMIT® II Plus Cannabinoid assay on the OLYMPUS® AU400™ System for the 50 ng/ml cutoff and the SYVA® 30R Biochemical System for the 20 ng/mL cutoff. The results demonstrated good agreement between each of the immunoassay methods.

The VITROS THC assay and the VITROS DAT Performance Verifiers have the following similarities to the predicate device: the same intended use, consist of liquid, ready to use reagents, have similar performance characteristics, are used on an automated clinical chemistry analyzer and calibrated against the same drug metabolite, 11-nor-delta-9-THC-9-COOH.

In addition to correlation studies, bench testing was performed to determine assay precision, linearity, specificity, limit of detection, and stability of the VITROS THC assay.

Table 1 Similarities and differences of the assays and control fluids performed using the new and predicate devices.

Device Similarities	
Device Characteristic	**Description**
Indications for Use	The assays are intended for use in the qualitative and semi-quantitative analysis of cannabinoids in human urine.
Test Principle	Homogeneous enzyme immunoassay
Sample Type	Human Urine
Reagent Format	Liquid ready to use
Antibody source	Mouse monoclonal antibodies reactive to delta 9-tetrahydrocannabinol
Calibrator analyte	11-nor-delta-9-THC-9-COOH
Calibrator and Control format	Refrigerated: Liquid, ready to use
Calibrator matrix	Human urine
Control matrix	Human urine

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Table 1(con't from previous page)

Device Differences		
Device Characteristic	**VITROS THC assay (New device)**	**SYVA EMIT II Plus Cannabinoid assay and Liquichek™ Controls (Predicate devices)**
Number of Calibrator levels	Six	Three for Qualitative Four for Semi-Quantitative
Instrumentation	VITROS 5,1 FS Chemistry Systems	Multiple clinical chemistry systems
Cutoff Values	20 and 50 ng/mL	20, 50, and 100 ng/mL
Cutoff Types	Qualitative and Semi-Quantitative for 20 and 50 ng/mL	Qualitative for 20, 50, and 100 ng/mL Semi-Quantitative for 50 and 100 ng/mL (OLYMPUS) Semi-Quantitative for the 20, 50, and 100 ng/mL (Syva 30R)
Control claimed analytes	Cocaine metabolites (benzoylecgonine), benzodiazepines (lormetazepam), methadone, amphetamines (d-methamphetamine), opiates (morphine), cannabinoids (11-nor-delta-9-THC-9-COOH), phencyclidine and barbiturates (secobarbital).	Methamphetamine, secobarbital, lormetazepam, tetrahydrocannabinol (THC), benzoylecgonine, ethanol, lysergic acid diethylamide (LSD), methadone, methaqualone, morphine, (Free), phencyclidine, propoxyphene, nortriptyline and addition of creatinine, pH, specific gravity.
Control: Number of levels	Five	Two

8. Conclusions The data presented in the premarket notification provide a reasonable assurance that the VITROS THC Reagent, VITROS Calibrator Kit 30, VITROS FS Calibrator 1 and VITROS DAT Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices. Equivalence to the predicates was demonstrated using a commercially available assay along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Michael M. Byrne, RAC
Regulatory Affairs MC00881
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100 Indigo Creek Drive
Rochester, NY 14626-5101

DEC 2 8 2006

Re: k063164
Trade Name: VITROS Chemistry Products THC Reagent, Calibrator Kit 30, FS calibrator 1, and DAT Performance Verifiers I, II, III, IV, and V
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid (THC) Test System
Product Code: LDJ, DLJ, DKB, Class II – DIF, Class I (reserved)
Dated: October 17, 2006
Received: October 18, 2006

Dear Mr. Byrne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
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Enclosure

Indications for Use

510(k) Number (if known): K063164

Device Name: VITROS Chemistry Products THC Reagent

Indications for Use:

For *in vitro* diagnostic use only. VITROS Chemistry Products THC Reagent is used on VITROS 5,1 FS Chemistry Systems for the semi-quantitative or qualitative determination of cannabinoids (THC) in human urine using a cutoff of either 20 ng/mL or 50 ng/mL. Measurements obtained with the VITROS THC method are used in the diagnosis and treatment of cannabinoid use or overdose.

The VITROS Chemistry Products THC assay is intended for use by professional laboratory personnel. It provides only a preliminary test result. A more specific alternative chemical method must be used to confirm a result obtained with this assay. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when evaluating a preliminary positive result.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K063164

Indications for Use

510(k) Number (if known): k063164

Device Name: VITROS Chemistry Products Calibrator Kit 30
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV and V

Indications for Use:

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 30 is used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative or semi-quantitative measurement of cannabinoids (THC).

For *in vitro* diagnostic use only. VITROS Chemistry Products FS Calibrator 1 is used in conjunction with VITROS Chemistry Products Calibrator Kits to calibrate VITROS 5,1 FS Chemistry Systems.

For *in vitro* diagnostic use only. VITROS Chemistry Products DAT Performance Verifiers are assayed controls used to monitor performance of urine drugs of abuse screening assays on VITROS 5,1 FS Chemistry Systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)